PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

St. Jude Medical AB
Patent Department
SE-175 84 Järfälla
SUEDE

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	07.07.2004
REPLY DUE	**within 2 month(s)** from the above date of mailing
Applicant's or agent's file reference: A02 P 2022 P	
International application No.: PCT/SE 03/01297	
International filing date *(day/month/year)*: 19.08.2003	
Priority date *(day/month/year)*: 27.09.2002	
International Patent Classification (IPC) or both national classification and IPC: A61N1/365	
Applicant: ST. JUDE MEDICAL AB et al	

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 27.01.2005

FRIST NOTERAD
2004 -09- 07

Sign:

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-16 as published

Claims, Numbers

1-13 as published

Drawings, Sheets

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 4-8

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☒ the claims, or said claims Nos. 4-8 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,2,10-13 (no)
Inventive step (IS)	Claims	3 (no)
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Concerning Sections III and V:

1. Reference is made to the following document:

   D1... US-A-4 869 252

2. Claim 1 is so vaguely drafted that document D1 reads onto it. Document D1 discloses an implantable cardioverter defibrillator including an autocapture mode of operation, the D1 system comprises

   - a pulse generator (cf. D1, fig.2 (36))
   - a defibrillation unit (cf. fig.1, (17))
   - sensing circuitry for sensing heart activity (fig.2, (37))
   - control unit (fig.1, (16)) for controlling timing and energy of the pacing pulses and cardioversion shocks,
   - a first operating mode being the autocapture mode of operation (cf. fig.4, of D1, blocks (87,88) and col.3, lines 21-24),
   - a second mode of operation in which pacing pulses according to predetermined pacing pulse settings are delivered (fig.4, block 81: pacing amplitude set to 4V),
   - the control unit is arranged for switching the system from said first operating mode into said second operating mode following delivery of a cardioversion shock (cf. fig.4: after defibrillation (block 93) the ICD switches into the second mode (block 81) of pacing at according to predetermined pacing settings) .

   Accordingly, the subject-matter of claim 1 lacks novelty and the requirement of Art.33(2) PCT is not met.

3. D1 also discloses the additional features as defined in current dependent claims 2,10-13 (Art.33(2) PCT not met):

   claim 2: mode switching after a predetermined time interval, see fig.4 of D1, block (93);
   claims 10-13: see figs.1,2 of D1

4. D1 does not mention the absolute time duration for the post defibrillation time out,

it appears however that suitable time intervals will be found by the skilled person by routine trial and error. Therefore, claim 3 is considered to lack an inventive step so that the requirement of Art.33(3) PCT is not met.

5. Claims 4 to 6 are indefinite with regard to the characteristic to be evaluated for extending PSD. As the sole parameter that has been disclosed is the amplitude of heart activity, these claims are not supported in the their entire scope by the disclosure of the application. An objection under Art.6 PCT thus arises. As claims 7 and 8 depend directly from the unsupported claims 4-6 no statement with respect to Art.33 PCT is feasible.

6. Claim 9 which defines the missing essential feature thus may be considered to meet the requirements of Art.6 PCT. As no available prior art document teaches to delay resumption of the autocapture mode after shock delivery as long as the heart signal amplitude remains below a certain threshold claim 9 could also be considered to meet the requirements of Art.33 PCT. The said feature avoids false determinations of pacing pulse amplitudes caused by an increased capture threshold immediately after shock.

7. For completeness, the independent claim 1 should be drafted in the correct two-part form with respect to D1 (Rule 6.3(b)(i),(ii) PCT) and D1 should be acknowledged in the description (Rule 5.1(a)(ii) PCT).